UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

LAUREN THOMPSON, Plaintiff v. REGENCE BLUESHIELD; EXPEDIA HEALTH & WELFARE BENEFIT PLAN; EXPEDIA, INC., in its capacity as Plan Administrator and/or Plan Sponsor; and MCMC SERVICES, LLC, Defendants.	No. 2:24-cv-1336 PLAINTIFF'S MOTION FOR TEMPORARY RESTRAINING ORDER

I. RELIEF REQUESTED

Plaintiff respectfully moves this Court pursuant to Federal Rule of Civil Procedure 65 and Local Rule 65 for a temporary restraining order enjoining Defendants from continuing to deny her urgently needed and life-saving medical care.

II. BACKGROUND AND OVERVIEW OF MOTION

This action arises under the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 *et seq*. Plaintiff is a 39-year-old mother of two young children. She has stage IV metastatic melanoma.

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Plaintiff receives medical services under an ERISA-governed plan that covers "medically necessary" care. The treatment at issue is squarely within the Plan's definition of that term.

Plaintiff's oncologist, Shailender Bhatia, M.D., prescribed an FDA-approved medication, nivolumab-relatlimab-rmbw. He explained in a detailed declaration why the medication is "medically necessary" – as the Plan defines that term – to treat Plaintiff's "refractory and life-threatening melanoma."

Defendants denied Plaintiff pre-authorization and coverage for treatment with nivolumab-relatlimab-rmbw. Their sole basis for doing so is that Plaintiff did not satisfy one criterion found in a guideline Defendant Regence BlueShield wrote regarding the medication – that the patient had "no prior systemic therapy for unresectable or metastatic disease."

As Dr. Bhatia explains, that criterion was imported from the original clinical trials of nivolumab-relatlimab-rmbw, *where it served to ensure a relatively homogenous cohort of patients during those trials*. "Clinical studies of medications often include such criterion; otherwise it would be difficult to determine the efficacy of the medication being tested." But, he continues, "*there is no rational basis to apply that criterion in the context of standard treatment*." Defendants' denial "of this FDA approved medication, especially given its proven effectiveness in metastatic melanoma, *is a completely arbitrary and irrational decision by the insurer with potential grave implications for Ms. Thompson's life*."

The very "guideline" regarding nivolumab-relatlimab-rmbw that Defendant Regence BlueShield relies upon states in red, underlined font: "Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control."

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The controlling contract language is the Plan's definition of the term "medically necessary." As set forth below in Section IV, treatment with nivolumab-relatlimab-rmbw is indisputably "medically necessary" under that definition.

III. EVIDENCE RELIED UPON

Plaintiff relies upon the Declaration of Shailender Bhatia, M.D., filed herewith. All facts set forth below regarding Plaintiff's diagnosis, condition and treatment are found in that declaration, which was submitted to Defendant Regence BlueShield during the appeal process. Dr. Bhatia is Director of the Melanoma and Renal Cancer Team at the Fred Hutchison Cancer Center; a Professor in the Clinical Research Division at the Fred Hutchison Cancer Center; and a Professor in the Division of Hematology and Oncology at the University of Washington School of Medicine. His c.v., including identification of his extensive clinical research and writing, is attached to his Declaration.

A copy of the Plan document cited below is attached to the Crawford Declaration.

IV. FACTS

A. The Plan's Definition of "Medically Necessary":

The Plan provides coverage for "medically necessary" services and supplies. It defines that term as follows:

> Medically Necessary or Medical Necessity means health care services or supplies that a Physician or other health care Provider, exercising prudent clinical judgment, would provide to a patient to prevent, evaluate, diagnose or treat an Illness, Injury, disease or its symptoms, and that are:
>
> • in accordance with generally accepted standards of medical practice. "Generally accepted standards of medical practice" means standards that are based on credible Scientific Evidence published in Peer-Reviewed Medical Literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians and other health care Providers practicing in relevant clinical areas and any other relevant factors.

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- clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's Illness, Injury or disease;

- not primarily for the convenience of the patient, Physician or other health care Provider; and

- not more costly than an alternative service or sequence of services or supply at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's Illness, Injury or disease.

Crawford Declaration, filed herewith, at Exhibit 1, numbered pages 59-60.

B. The Requested Treatment is Medically Necessary and Urgently Needed:

Dr. Bhatia's August 19, 2024, Declaration describes Plaintiff's medical condition and explains why the treatment he and his colleagues at the Fred Hutchison Cancer Center prescribed is "medically necessary" as that term is defined immediately above. He states:

> My colleagues and I at the Fred Hutch Cancer Center provide medical care to Lauren C. Thompson, DOB [redacted]. Ms. Thompson, a 39-year-old mother of two young children, has life-threatening, stage IV metastatic melanoma. She has rapidly progressing disease despite prior treatment with ipilimumab, nivolumab, binimetinib, and tumor infiltrating lymphocytes under a clinical trial. Her melanoma is unresectable, and without effective systemic therapy this young patient's life is at serious risk.
>
> It is my professional judgment, and that of our multi-disciplinary oncology team at the Fred Hutch Cancer Center – a team that includes thought leaders in melanoma – that nivolumab-relatlimab-rmbw (Opdualag) is a highly appropriate FDA-approved therapy for Ms. Thompson's refractory and life-threatening melanoma. We have prescribed this treatment, but unfortunately the insurer has repeatedly denied pre-authorization. Copies of our two prior appeals are attached at TABS 2 and 3.[1]
>
> It is our prudent clinical judgment that providing this medication to Ms. Thompson is squarely in accordance with generally accepted standards of

[1] The ten numbered attachments to Dr. Bhatia's Declaration are filed herewith as numbered exhibits to his Declaration.

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medical practice. We have several patients in our clinic who received this combination for their refractory melanoma (not front-line setting) and experienced complete remission (i.e. no visible tumors left behind), which has been life saving for these patients. In addition to our own clinical experiences, there are several credible scientific studies published in medical journals that meet nationally recognized requirements for scientific manuscripts, and which submit most of their published articles for review by experts who are not part of the editorial staff, that show strong data regarding the efficacy of nivolumab-relatlimab-rmbw in both front-line *and in refractory melanoma patients*. See Ascierto PA, et al., Nivolumab and Relatlimab in Patients With Advanced Melanoma That Had Progressed on Anti-Programmed Death-1/Programmed Death Ligand 1 Therapy: Results From the Phase I/IIa RELATIVITY-020 Trial. J Clin Oncol. 2023 May 20;41(15):2724-2735. doi: 10.1200/JCO.22.02072. Epub 2023 Feb 13. PMID: 36780608; PMCID: PMC10431305 (copy attached at TAB 4), reporting on a clinical study that concluded, "Nivolumab and relatlimab had a manageable safety profile and ***demonstrated durable clinical activity in a proportion of patients with heavily pretreated advanced melanoma*** with prior progression on anti-PD-(L)1-containing regimens." See also Xu J, Mu S, Wang Y, Yu S, Wang Z. Recent advances in immunotherapy and its combination therapies for advanced melanoma: a review. Front Oncol. 2024 Jul 16;14:1400193. doi: 10.3389/fonc.2024.1400193. PMID: 39081713; PMCID: PMC11286497 (copy attached at TAB 5), stating that for "advanced melanoma patients who have progressed *after receiving previous treatment* (including anti-PD-1 therapy), relatlimab combined with nivolumab can also bring long-lasting survival benefits." See also Sorino C, Iezzi S, Ciuffreda L, Falcone I. Immunotherapy in melanoma: advances, pitfalls, and future perspectives. Front Mol Biosci. 2024 Jun 28;11:1403021. doi: 10.3389/fmolb.2024.1403021. PMID: 39086722; PMCID: PMC11289331 (copy attached at TAB 6) noting that "the combination of relatlimab and nivolumab had satisfactory and durable clinical results in patients with metastatic melanoma *that were previously treated with PDL-1 inhibitors*."

Our determination that nivolumab-relatlimab-rmbw is medically necessary to treat Ms. Thompson's metastatic melanoma is not only in accordance with generally accepted standards of medical practice, and based on credible scientific studies published in nationally recognized medical journals, but also supported by the United States Food and Drug Administration ("the FDA"), which has approved nivolumab-relatlimab-rmbw for treatment of

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> stage IV melanoma, *regardless of the line of therapy*. See the FDA label at TAB 7.
>
> Further, use of nivolumab-relatlimab-rmbw for metastatic melanoma is supported by national guidelines, including the National Comprehensive Cancer Network. See page 54 of the NCCN Guidelines Version 2.2024, for Melanoma: Cutaneous, identifying the medication as a "*preferred regimen*" for "*second-line or subsequent therapy*" for metastatic or unresectable melanoma, at TAB 8.
>
> Treatment with nivolumab-relatlimab-rmbw is unquestionably clinically appropriate given the type, extent, site and duration of Ms. Thompson's disease and considered effective for her disease.
>
> We have not recommended nivolumab-relatlimab-rmbw for our convenience, or the convenience of the patient or any other health care provider.
>
> There is *no FDA-approved alternative service or sequence of services that is as likely to produce equivalent therapeutic results* or to be as effective in the treatment of Ms. Thompsons's refractory melanoma.

Declaration of Shailender Bhatia, ¶¶ 3-11.

C. Defendants Relied on an Irrational and Arbitrary Criterion Not Found in the Plan Document to Deny Plaintiff the Treatment at Issue.

Dr. Bhatia's Declaration also explained why the criterion Regence BlueShield cited when denying Plaintiff coverage for nivolumab-relatlimab-rmbw has no rational application in the context of treatment, as opposed to clinical trials in which medications are tested:

> This second criterion – that the patient had no prior systemic therapy – is imported from the RELATIVITY-047 clinical trial of nivolumab-relatlimab-rmbw, where the criteria to participate in that trial included that patients "must not have had prior systemic anticancer therapy for unresectable or metastatic melanoma." See TAB 9, Tawbi HA, et al., RELATIVITY-047 Investigators, Relatlimab and Nivolumab versus Nivolumab in Untreated Advanced Melanoma. N Engl J Med. 2022 Jan 6;386(1):24-34. doi: 10.1056/NEJMoa2109970. PMID: 34986285; PMCID: PMC9844513, and TAB 10, the appendix to that article detailing the inclusion criteria. This

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> particular criterion was rational *in the context of clinical trials*, in order to ensure a relatively homogenous cohort of patients. Clinical studies of medications often include such criterion; otherwise it would be difficult to determine the efficacy of the medication being tested. But there is no rational basis to apply that criterion in the context of *standard treatment*. When there are multiple FDA-approved treatment options available for a patient, one regimen will have to be chosen as the first-line option, and others will have to be used sequentially, as needed based on the response to prior regimen(s). In the case of Ms. Thompson, we chose ipilimumab plus nivolumab, also a standard treatment option regardless of the line of therapy, as the first treatment option for her metastatic disease. Denial of this FDA approved medication, especially given its proven effectiveness in metastatic melanoma, is a completely arbitrary and irrational decision by the insurer with potential grave implications for Ms. Thompson's life.

Declaration of Shailender Bhatia, ¶ 12 (emphasis in original).

The *only* basis on which Defendants denied coverage for nivolumab-relatlimab-rmbw is this criterion it incorrectly imported into its guidelines – that the patient had no prior systemic treatment. Each of their four decisions recite that basis, and that basis only:

July 10, 2024, Initial denial: Regence BlueShield denied Dr. Bhatia's request that it authorize coverage for nivolumab-relatlimab-rmbw on July 10, 2024, stating:

> **The reason for this decision**
>
> Our clinical staff reviewed all the information provided and determined that the medication policy criteria were not met. Specifically, we recognize your patient has metastatic melanoma. However, based on the information provided we are unable to establish that:
>
> - your patient has had no prior systemic treatment in the advance setting.
>
> . . .
>
> Coverage criteria
>
> The medication policy for nivolumab-relatlimab-rmbw (Opdualag) states that nivolumab-relatlimab-rmbw (Opdualag) may be covered when:

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- there is a diagnosis of melanoma, unresectable or metastatic.
- no prior systemic therapy in the advanced disease setting.
- nivolumab-relatlimab-rmbw (Opdualag) will be used as monotherapy.

Crawford Declaration, Exhibit 2.

July 19, 2024, Appeal Denial: Regence BlueShield denied Plaintiff's first appeal on July 19, 2024, stating:

> **Why this authorization request was denied**
> Our clinical staff reviewed all the information provided and determined that the medication policy criteria were not met. As previously stated, we recognize that you have metastatic melanoma despite use of binimetinib, Opdivo and Yervoy. However, based on the information submitted by your provider we are unable to determine that:
>
> - you have not had prior therapy in the advanced setting.
>
> Coverage criteria
> The medication policy for nivolumab-relatlimab-rmbw (Opdualag) states that nivolumab-relatlimab-rmbw (Opdualag) may be covered when:
> - there is a diagnosis of melanoma, unresectable or metastatic.
> - there has been no prior systemic therapy in the advanced disease setting.
> - nivolumab-relatlimab-rmbw (Opdualag) will be used as monotherapy.

Crawford Declaration, Exhibit 3.

August 6, 2024, Second Appeal Denial: Regence BlueShield denied Plaintiff's second appeal on August 6, 2024, stating:

> The reason is the criteria for medical necessity have not been met. The clinical documents we received from your doctor show you have had prior systemic (affecting the entire body) therapy in the advanced disease setting. The clinical records indicate that you have had three prior lines of medication therapy utilizing binimetinib, Opdivo (nivolumab) and Yervoy (ipilimumab). Opdualag (nivolumab-relatlimab-rmbw) is being requested in the fourth line setting as monotherapy (the use of a single drug to treat a particular disorder or disease) to treat your metastatic melanoma (skin cancer that has spread from a primary site). Opdualag is considered not medically necessary when there has been prior systemic therapy in the advanced disease setting.

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Crawford Declaration, Exhibit 4.

August 23, 2024 IRO Level Denial: Defendant's chosen "Independent Review Organization," MCMC Services, LLC, opined that treatment with nivolumab-relatlimab-rmbw did "not meet the plan definition of a medically necessary treatment" because "only limited evidence is available to suggest that this treatment can improve health outcomes, not enough to support use of this treatment as a standard of care treatment for patients who have been previously treated for metastatic melanoma, particularly those who have undergone multiple prior treatments." Crawford Declaration, Exhibit 5.

The anonymous reviewer engaged by MCMC Services, LLC, did not address the fact that the "no prior systemic therapy in the advanced disease setting" criterion was imported from the clinical criteria for inclusion in the first clinical trials of the medication. Nor did they address or refute Dr. Bhatia's statement that the Fred Hutch Cancer Center has "several patients in our clinic who received this combination for their refractory melanoma (not front-line setting) and experienced complete remission (i.e. no visible tumors left behind), which has been life saving for these patients." Nor did they address the fact that the United States Food and Drug Administration has approved nivolumab-relatlimab-rmbw for treatment of stage IV melanoma, *regardless of the line of therapy*, or that use of nivolumab-relatlimab-rmbw for metastatic melanoma is supported by national guidelines, including the National Comprehensive Cancer Network, which identified the medication as a "preferred regimen" for "*second-line or subsequent therapy*" for metastatic or unresectable melanoma. Their observation that there is "limited" evidence regarding the efficacy of nivolumab-relatlimab-rmbw overlooks that the medication is new, and accordingly not subject to extensive medical literature – and that what literature does exist states *it is effective in patients who have had*

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prior systemic therapy. See Dr. Bhatia's Declaration at ¶5 and Exhibits 4-6 of that Declaration. The anonymous MCMC Services, LLC reviewer simply rubber-stamped Regence BlueShield's decision.

V. LEGAL AUTHORITY AND ARGUMENT

A. This Case Fulfills the Requirements for Injunctive Relief.

The legal standards that apply to injunctions apply to temporary restraining orders as well. *Stuhlbarg Int'l Sales Co. v. John D. Brush & Co., Inc*., 240 F.3d 832, 839 n.7 (9th Cir. 2001) (preliminary injunction and temporary restraining order standards are "substantially identical"). To obtain a preliminary injunction, a plaintiff must show that (1) they are "likely to succeed on the merits"; (2) they are "likely to suffer irreparable harm in the absence of" a preliminary injunction; (3) "the balance of equities tips in [their] favor"; and (4) a preliminary injunction "is in the public interest." *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1127 (9th Cir. 2009) (quoting *Winter v. Nat. Res. Def. Council, Inc*., 555 U.S. 7, 23 (2008)). The Ninth Circuit uses a "sliding scale" approach to preliminary injunctions, which deemphasizes the importance of the first *Winter* factor.

> [I]f a plaintiff can only show that there are "serious questions going to the merits"—a lesser showing than likelihood of success on the merits—then a preliminary injunction may still issue if the "balance of hardships tips sharply in the plaintiff's favor," and the other two *Winter* factors are satisfied.

Shell Offshore, Inc. v. Greenpeace, Inc., 709 F.3d 1281, 1291 (9th Cir. 2013) (quoting *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011)). "Under the 'sliding scale' variant of the *Winter* standard, if a plaintiff can only show that there are serious questions going to the merits – a lesser showing than likelihood of success on the merits – then a preliminary injunction may still issue if the balance of hardships tips *sharply* in the plaintiff's

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favor, and the other two *Winter* factors are satisfied." *Alliance for the Wild Rockies v. Pena*, 865 F.3d 1211, 1217 (9th Cir. 2017) (quotation marks and citations omitted; italics in original).

Plaintiff must establish that the risk of irreparable harm is "likely, not just possible." *Alliance for the Wild Rockies*, 632 F.3d at 1131. "Irreparable harm is traditionally defined as harm for which there is no adequate legal remedy, such as an award of damages." *Arizona Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1068 (9th Cir. 2014).

Plaintiff meets her burden on all four elements.

(1) Likelihood of success on the merits: It is highly likely Plaintiff will succeed on the merits, as Defendants' only basis for denying coverage was its misplaced reliance on a criterion for inclusion in clinical trials, a criterion that is irrational in the context of treatment. Dr. Bhatia's declaration demonstrates that treatment with nivolumab-relatlimab-rmbw satisfies every element in the Plan's definition of "medical necessity." He concluded, "[i]n summary, nivolumab-relatlimab-rmbw is medically necessary to try to control Ms. Thompson's life-threatening cancer. Its use in patients with systemic therapy is well-supported by scientific evidence, is FDA approved and in accordance with national guidelines."

(2) Likelihood of irreparable harm: Plaintiff will suffer irreparable harm if the treatment is not immediately ordered. Dr. Bhatia's declaration concluded:

> Denying this treatment will have grave life-threatening consequences to this young patient's health. There is already a major delay in her care due to the insurer's repeated negligence of their responsibility, despite repeated pleas by our medical team.

Declaration of Dr. Bhatia at ¶ 13.

(3) Balance of equities: If Defendants are not enjoined from continuing to withhold benefits under the Plan, Plaintiff's very life is in danger. As Dr. Bhatia states, "without

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effective systemic therapy this young patient's life is at serious risk" from her "rapidly progressing disease" of "refractory and life-threatening melanoma." Declaration of Dr. Bhatia at ¶¶ 3-4. It is difficult to conceive of equities to place on Defendants' side of the scale. Whatever they may be, they cannot outweigh saving the life of a 39 year-old mother of two young children. The harm to Plaintiff if the requested relief is not granted far outweighs the slight harm to the Plan. There is no remedy at law that can protect or save Plaintiff's life.

(4) Public Interest: "[T]he insurance business is 'affected with a public interest and offers services of a quasi-public nature[.]'" *Amadeo v. Principal Mut. Life Ins. Co*., 290 F.3d 1152, 1161 (9th Cir. 2002) (quoting *Fletcher v. W. Nat'l Life Ins. Co*., 10 Cal.App.3d 376 (1970)). The public interest is served by promoting rational and informed review of medical claims, and insurers and claims administrators should not be permitted to disregard medical evidence or the plan terms. Enjoining Defendants' arbitrary and irrational denial of coverage advances the public interest in fulfilling ERISA's command that plan fiduciaries discharge their duties in respect to claims processing "solely in the interests of the participants and beneficiaries" of the Plan. 29 U.S.C. § 1104(a)(1). The public interest is also served by ordering such relief, as it underscores ERISA's requirement that administrators provide a "full and fair review" of claim denials. 29 U.S.C. §1133(2).

B. Injunctive Relief Should Issue Under the Circumstances Presented Here.

In *Wilson v. Group Hospitalization and Medical Services, Inc*., 791 F. Supp. 309 (D.D.C. 1992), the court issued a preliminary injunction in favor of a breast cancer patient seeking high dose chemotherapy upon finding that the plaintiff would likely prevail on the merits, that the patient would die if therapy were discontinued, that the insurer would not

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suffer substantial injury, and that the public interest would be served. There, as here, the overriding factor involved the risk of death to the insured. *Id*. at 313-14.

In *Bowen v. Consol. Elec. Distributors, Inc. Emp. Welfare Ben. Plan*, 461 F. Supp. 2d 1179 (C.D. Cal. 2006), the court issued a preliminary injunction ordering medical treatment that her health plan had deemed not "medically necessary." It found the balance of hardships tipped decidedly in claimant's favor; that she met her burden of demonstrating that there was at least a serious question as to whether she was improperly denied coverage of intravenous medications; and waived the bond requirement.

In *White v. Caterpillar, Inc*., 765 F. Supp. 1418 (W.D. Mo. 1991), a breast cancer patient was denied coverage for treatment based upon the Plan's belief that it was "investigational" and not an accepted medical practice. The court found that injunctive relief was appropriate since denial of coverage would likely result in the plaintiffs death, that the denial of coverage was arbitrary and that plaintiff would likely prevail on the merits, that her condition was sufficiently rare that it would not result in a flood of coverage claims, and that it was in the public interest to see that the cost of properly covered treatment was provided to insureds.

In *Smith v. Newport News Shipbuilding Health Plan, Inc.*, 148 F. Supp. 2d 637 (E.D. Va. 2001), the court issued a preliminary injunction ordering treatment of the plaintiff's stage II breast cancer with high-dose chemotherapy, finding that the balance of hardships weighed heavily in favor of granting preliminary injunction and that there was serious question as to whether the plan administrator abused its discretion in interpreting the plan so as to deny coverage. The court required the patient to post bond of zero dollars in connection with issuance of the preliminary injunction.

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C. The Benefit Determination Must be Based on the Plan Definition of "Medically Necessary" and not Regence BlueShield's Guidelines.

ERISA's "statutory scheme . . . 'is built around reliance on the face of written plan documents.'" *US Airways, Inc. v. McCutchen*, 569 U.S. 88, 100–01 (2013), quoting *Curtiss–Wright Corp. v. Schoonejongen,* 514 U.S. 73, 83 (1995). *See* 29 U.S.C. § 1102(a)(1): "[e]very employee benefit plan shall be established and maintained pursuant to a written instrument." Plan administrators must act "in accordance with the documents and instruments governing the plan[.]" 29 U.S.C. § 1104(a)(1)(D). ERISA's legislative history underscores the primacy of written plan terms:

> In the words of the key congressional report, "[a] written plan is to be required in order that every employee may, *on examining the plan documents,* determine exactly what his rights and obligations are under the plan." H.R.Rep. No. 93–1280, p. 297 (1974) U.S. Code Cong. & Admin.News pp. 4639, 5077, 5078 (emphasis added).

Curtiss–Wright Corp., 514 U.S. at 83 (emphasis and alterations in original).

The Supreme Court has repeatedly emphasized the paramount nature of written plan terms, and made clear that those terms establish the rights of ERISA plan participants and govern the obligations of ERISA plan administrators and fiduciaries. *See*, *e.g.*, *Heimeshoff v. Hartford Life & Acc. Ins. Co.*, 571 U.S. 99 (2013):

> "The plan, in short, is at the center of ERISA." *US Airways, Inc. v. McCutchen,* 569 U.S. ——, ——, 133 S.Ct. 1537, 1548, 185 L.Ed.2d 654 (2013). "[E]mployers have large leeway to design disability and other welfare plans as they see fit." *Black & Decker Disability Plan v. Nord,* 538 U.S. 822, 833, 123 S.Ct. 1965, 155 L.Ed.2d 1034 (2003). And once a plan is established, the administrator's duty is to see that the plan is "maintained pursuant to [that] written instrument." 29 U.S.C. § 1102(a)(1). This focus on the written terms of the plan is the linchpin of "a system that is [not] so complex that administrative costs, or litigation expenses, unduly discourage employers from offering [ERISA] plans in the first place." *Varity Corp. v. Howe,* 516 U.S. 489, 497, 116 S.Ct. 1065, 134 L.Ed.2d 130 (1996).

571 U.S. at 108 (all alterations in original).

The "guideline" regarding nivolumab-relatlimab-rmbw that Defendant Regence BlueShield relies upon states in red, underlined font: "Benefit determinations should be based

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in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control." That is correct. The controlling contract language is the Plan's definition of "Medically Necessary." For the reasons set forth above in Sections 4.A and 4.B, the treatment at issue is medically necessary under that definition.

D. The Bond Should Be Waived.

"The district court is afforded wide discretion in setting the amount of the bond, *Walczak v. EPL Prolong, Inc*., 198 F.3d 725, 733 (9th Cir.1999), and the bond amount may be zero if there is no evidence the party will suffer damages from the injunction. *Gorbach v. Reno*, 219 F.3d 1087, 1092 (9th Cir. 2000)." *Connecticut Gen. Life Ins. Co. v. New Images of Beverly Hills*, 321 F.3d 878, 882 (9th Cir. 2003). A strong likelihood of success on the merits also may justify the waiver of a bond. *Scherr v. Volpe*, 466 F.2d 1027, 1035 (7th Cir. 1972).

Plaintiff requests that the bond be waived or, if a bond is required, that the Court exercise its discretion and require one of a nominal amount only.

VI. COMPLIANCE WITH FRCP 65 AND LOCAL RULE 65

"Motions for temporary restraining orders without notice to and an opportunity to be heard by the adverse party are disfavored and will rarely be granted." Local Rules W.D. Wash. 65(b)(1). A court may issue a TRO without notice to the adverse party and an opportunity for them to be heard only if the requirements of Fed. R. Civ. P. 65(b) are satisfied. *Id*. Federal Rule of Civil Procedure 65(b) outlines two requirements for a court to issue a temporary restraining order without notice to the adverse party: first, "specific facts in an affidavit or a verified complaint [must] clearly show that immediate and irreparable

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injury, loss, or damage will result to the movant before the adverse party can be heard in opposition[,]" and second, "the movant's attorney certifies in writing any efforts made to give notice and the reasons why it should not be required." Unless these requirements are satisfied, "the moving party must serve all motion papers on the opposing party before or contemporaneously with the filing of the motion and include a certificate of service with the motion." Local Rules W.D. Wash. 65(b)(1).

Plaintiff has alleged specific facts clearly showing that further delay in receiving the treatment will cause immediate and irreparable injury. Her counsel has made the following efforts to serve each Defendant with her motion papers and her Complaint:

Defendant Expedia Health & Welfare Benefit Plan: Plaintiff's counsel has transmitted copies of the Complaint, this Motion and the supporting declarations via email to the two Expedia employees identified as the Plan Administrator in Plan documents and Plan filings with the U.S. Department of Labor.

Defendant Expedia, Inc.: This Defendant is sued in its capacity as Plan Administrator and Plan Sponsor. As stated immediately above, Plaintiff's counsel has transmitted copies of the Complaint, this Motion and the supporting declarations via email to the two Expedia employees identified as the Plan Administrator.

Defendant Regence BlueShield: Plaintiff's counsel has transmitted the Complaint and Motion to the "Regence - MEDICAL DRUG REVIEWS APPEALS" fax number (844-629-4406) and to the Regence "ASO Appeals and Grievances" fax number (877-663-7526). Plaintiff's counsel is *not* faxing the supporting Declaration of Dr. Bhatia, as that document was sent to both fax numbers on August 19 and 20, 2024, as part of Plaintiff's IRO level appeal. Plaintiff's counsel is arranging for service of the papers on Regence BlueShield's

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registered agent, Corporation Service Company, in Tumwater, Washington and will advise the Court when that service has occurred. Plaintiff's counsel has sent the Complaint, Motion and supporting declarations to a local Seattle attorney who represents RegenceBlue Shield in other matters and asked for her assistance to see that the papers are provided to the appropriate person(s) at Regence BlueShield.

Defendant MCMC Services, LLC: Plaintiff's counsel has transmitted the Complaint and Motion to the fax number for this business (301-652-1250). Plaintiff's counsel is *not* faxing the supporting Declaration of Dr. Bhatia, as that document was already provided to MCMC Services, LLC as part of Plaintiff's IRO level appeal. Plaintiff's counsel is also arranging for service of the papers on MCMC Services, LLC's registered agent, Corporation Service Company, in Tumwater, Washington and will advise the Court when that service has occurred.

VII. CONCLUSION

The equities in this case compel the conclusion Defendants should be ordered to provide coverage for nivolumab-relatlimab-rmbw until the Court can make a determination on the merits of the suit. Plaintiff respectfully requests that the Court grant a temporary restraining order so ordering, and waive the bond requirement. A proposed order is attached to this filing and will be emailed to the Court once the case has been assigned.

RESPECFULLY SUBMITTED this 26th day of August 2024.

LAW OFFICE OF MEL CRAWFORD

By s/*Mel Crawford*
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I certify that this memorandum contains 4,956 words, in compliance with the Local Civil Rules.

s/*Mel Crawford*
Mel Crawford

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